No. 17-8151

IN THE

Supreme Court of the United States

RUSSELL BUCKLEW,

Petitioner,

v.

ANNE L. PRECYTHE, DIRECTOR, MISSOURI DEPARTMENT OF CORRECTIONS, ET AL.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Eighth Circuit

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

JEFFREY K. FRANCER
ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Ave., NW
Washington, DC 20001

BRIAN T. BURGESS
Counsel of Record
JAIME A. SANTOS
ANDREW KIM
GOODWIN PROCTER LLP
901 New York Ave., NW
Washington, DC 20001
(202) 346-4000
bburgess@goodwinlaw.com

Counsel for Amicus Curiae

July 23, 2018

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INTEREST OF THE *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines, active pharmaceutical ingredients, as well as suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM's members provide patients with access to generic and biosimilar medicines that are as safe and effective as their brand-name counterparts at a substantially more affordable price. Generic drugs now constitute 90% of all prescriptions dispensed in the United States, yet they account for only 23% of total drug spending. Over the last decade, generic and biosimilar drugs have generated $1.68 trillion in savings for patients and taxpayers. AAM's core mission is to improve the lives of consumers by providing access to affordable medicines used for therapeutic purposes. To further that mission, AAM regularly participates in litigation as an *amicus curiae*.

This case concerns an as-applied challenge to the State of Missouri's use of a lethal injection protocol featuring the drug pentobarbital. AAM takes no position on the propriety of capital punishment. But AAM and its members strongly oppose the use of their medicines—which are researched and developed to enhance patient health—to carry out executions. Indeed, many pharmaceutical companies, including numerous AAM

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[1] Pursuant to Rule 37.6, *amicus* affirms that no counsel for a party authored any part of this brief, and that no person other than *amicus*, its members, or its counsel made a monetary contribution intended to fund its preparation or submission. All parties have filed blanket consents to the filing of *amicus curiae* briefs.

members, prohibit the sale of their products for the purpose of lethal injection, either directly or indirectly through distributors.[2] These AAM members recognize that the diversion of their medicines for use in execution protocols is contrary to their business interests as well as their ethical duties.

Using drug products for lethal injection is inconsistent with the rigorous process for studying and approving prescription drugs in this country, as administered by the U.S. Food and Drug Administration ("FDA"). The drugs that are used for lethal injection—such as sedatives, anticonvulsants, barbiturates, muscle relaxants, and potassium supplements—are approved to treat or aid in the treatment of particular health conditions. The off-label use of those drugs to kill rather than to heal is a perversion of their therapeutic purpose, which AAM firmly opposes.

SUMMARY OF ARGUMENT

Drug manufacturers overwhelmingly oppose the use of their products for lethal injections. And for good reason. FDA-approved drugs are studied and labeled for the treatment of specific illnesses and conditions. As part of the initial approval process, pharmaceutical products are rigorously tested to ensure that they are safe and effective for particular indications. Unsurprisingly, no prescription drug has been tested (or approved by regulators) at the very high doses typically employed in an execution protocol.

Nor is lethal injection a medically accepted off-label use of the powerful injectable drugs used as part of execution protocols. Responsible off-label prescribing of a

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[2] *See* Lethal Injection Information Center, *Industry Statements*, http://lethalinjectioninfo.org/industry-statements/.

drug requires empirical testing and scientific proof that the drug is safe and effective for treating a particular condition. And the prescription must be informed by sound medical judgment to consider how a patient's individual characteristics might affect the drug's safety and efficacy. Neither requirement is satisfied when drugs are used for capital punishment. We are not aware of any adequate or well-controlled scientific study that has been conducted on the safety and efficacy of injectable drugs when used as part of an execution protocol. Moreover, lethal injections often take place without adequate medical supervision, since many doctors and other primary care providers believe that participating in capital punishment would violate their ethical obligations. Indeed, that is the position taken by the leading professional organizations, including the American Medical Association and the American Society of Anesthesiologists.

Like doctors and other medical professionals, many drug manufacturers (including the members of AAM) recognize that they have an ethical obligation to ensure that their products are used only to heal, not to harm. Yet despite many manufacturers' best efforts, drugs that are essential to the healthcare system—including some that are in short supply—have been diverted to state prison systems for use in capital punishment. AAM and its members cannot support such misuse of their products.

ARGUMENT

I. The Use Of Prescription Drugs In Executions Is Inconsistent With The Premises Underlying FDA Review Of Such Drugs.

Drug regulation in the United States is built on FDA's "rigorous evaluation process, which scrutinizes everything about [a] drug" before it can be released into the market.[3] Under the Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040, as amended 21 U.S.C. § 301 *et seq.*, drug manufacturers must gain approval from FDA before marketing a prescription drug in interstate commerce. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013) (citing 21 U.S.C. § 355(a)). By statute, drugs must be dispensed by prescription when they are of sufficiently high risk that they are "not safe for use except" under appropriate medical supervision. 21 U.S.C. § 353(b)(1). As part of FDA-approval process, the manufacturer filing a new drug application ("NDA") must put forward evidence from "investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." *Id.* § 355(b)(1).

In their applications to FDA, drug manufacturers seeking approval of a new product pursuant to a NDA must submit labeling that specifies the drug's intended use. 21 U.S.C. § 355(b)(1)(F). And the clinical studies conducted to secure approval must establish the drug's safety and efficacy for that designated use. Thus, applicants must submit "[s]tudies of the pharmacological actions of the drug in relation to its proposed therapeu-

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[3] FDA, *The FDA's Drug Review Process* (Nov. 24, 2017), https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm.

tic indication," "[s]tudies of the toxicological effects of the drug as they relate to the drug's intended clinical uses," and "studies of toxicities related to the drug's particular mode of administration or conditions of use." 21 C.F.R. § 314.50(d)(2)(i)-(ii).

Generic drug manufacturers, in turn, are permitted to rely on those studies of safety and efficacy to receive FDA approval by establishing that the generic drug is the same as the brand-name drug in all material respects, including that the generic drug will be used for the same indication and has the same dosage, strength, and method of administration as a previously approved drug. 21 U.S.C. § 355(j)(2)(A)(i)-(iv). Any change to the active ingredient, the route of administration, dosage form, or strength may require additional testing for safety and efficacy. *Id.* § 355(j)(2)(C).

Taken as a whole, the FDCA and FDA regulations are designed "to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

A. The Prescription Drugs Used For Lethal Injection Have Not Been Designed, Tested, Or Approved To Carry Out Executions.

FDA does not approve drugs for use in capital punishment, and manufacturers do not study how these drugs will function in that unusual setting. Consider, for example, the approved uses of several drugs that states often use in executions.

- Pentobarbital—the drug Respondents intend to use to execute Petitioner—is a barbiturate drug indicated as a sedative, a short-term treatment

for insomnia, a pre-anesthetic, and an emergency treatment for "certain acute convulsive episodes," such as those associated with eclampsia, tetanus, or meningitis.[4]

- Midazolam, the injectable drug at issue in *Glossip v. Gloss*, 135 S. Ct. 2726 (2015), is also a sedative (although not a barbiturate), and is often used continuously during surgery.[5]
- Muscle relaxants, such as pancuronium bromide, are used in conjunction with general anesthesia—particularly to facilitate tracheal intubation, which prevents a patient from asphyxiating and allows for continuous breathing.[6]
- Potassium-based injectable drugs, such as potassium chloride, are used to treat potassium deficiency in controlled settings; medical supervision is important to prevent hyperkalemia,

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[4] *See* U.S. Nat'l Library of Med., *Pentobarbital Sodium* (Sagent Pharm.), NDC Codes 25021-676-20, 25021-676-50, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid =e9f4b344-b092-4eec-b49d-d8cfe8ebc05d.

[5] *See* Br. of Sixteen Professors of Pharmacology as Amicus Curiae in Support of Neither Party at 10-11, *Glossip v. Gloss*, No. 14-7955, at 10-11 (U.S. filed Mar. 16, 2015) ("Benzodiazepines [such as midazolam] are CNS depressants that reliably provide sedative, hypnotic, muscle relaxant, anxiety inhibitory, and anticonvulsant effects.").

[6] *See* U.S. Nat'l Library of Med., *Pancuronium Bromide* (Hospira, Inc.), NDC Code 0409-4646-01, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d705382b-8aa0-4893-ed9ebcf7c7d9d0a2.

which can cause cardiac arrhythmia and, eventually, cardiac arrest.[7]

In the hands of corrections officials, however, these drugs are not used for their indicated or other medically appropriate purposes. Far from it. For example, instead of using pentobarbital as a sedative and an anticonvulsant, corrections officials use the drug to stop a prisoner from breathing and to stop his or her heart. Pet. App. 11a.

Likewise, corrections officials use midazolam as the single anesthetic in a three-drug protocol, even though it has never been studied, recommended, or approved for use as a sole anesthetic, much less as an anesthetic used to facilitate death. *See Glossip*, 135 S. Ct. at 2742; *id.* at 2783 (Sotomayor, J., dissenting) (noting that midazolam "is not approved by the [FDA] for use as, and is not in fact used as, a sole drug to produce and maintain anesthesia in surgical proceedings" (quotation marks omitted)); *Arthur v. Dunn* 137 S. Ct. 725, 726 (2017) (Sotomayor, J., dissenting) ("Although it can be used to render individuals unconscious, midazolam is not used on its own to *maintain* anesthesia . . . in surgical procedures, and indeed, the [FDA] has not approved the drug for this purpose.").

Pancuronium bromide, in turn, is used by corrections officials to stop prisoners from breathing entirely—a significant departure from its approved use to paralyze the breathing muscles merely so that a pa-

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[7] *See* U.S. Nat'l Library of Med., *Potassium Chloride* (Baxter Healthcare Corp.), NDC Codes 0338-0703-41, 0338-0703-48, 0338-0705-41, 0338-0705-48, 0338-0707-48, 0338-0709-48, *available at* https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=092ddee4-572d-4771-8d95-880cea01097e.

tient can breathe by other means.[8] And potassium-based drugs, which are typically administered under close medical supervision to prevent a patient from suffering cardiac arrest, are instead used by corrections officials to induce heart attacks and ultimately to stop a prisoner's heart.[9]

Not only have these drugs never been tested for use in capital punishment, but the doses required to repurpose them for executions often have not been clinically studied or approved. The standard injectable dose of pentobarbital, for example, is somewhere between 150 and 200 milligrams.[10] In contrast, corrections officials typically use over 25 to 50 times that amount—5 to 10 grams—when administering the drug to execute a prisoner. *See Bucklew v. Lombardi*, 565 F. App'x 562, 566 (8th Cir. 2014) ("[F]ive grams of pentobarbital are injected into the line. . . . If the five grams of pentobarbital do not result in death, an additional five grams are injected into the line."), *vacated on reh'g en banc*, 783 F.3d 1120 (8th Cir. 2015). Similarly, the normal dose of midazolam for a healthy adult is be-

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[8] *See Baze v. Rees*, 553 U.S. 35, 44 (2008) (noting pancuronium bromide is used as the second drug in a three-drug protocol to "paralyz[e] the diaphragm" and "stop[] respiration"); Casey Lynne Ewart, Note, *Use of the Drug Pavulon in Lethal Injections: Cruel and Unusual?*, 14 Wm. & Mary Bill of Rts. J. 1159, 1183 (2006) ("Pancuronium bromide can stop a person's breathing by paralyzing his lungs and diaphragm.").

[9] *Baze*, 553 U.S. at 44 ("Potassium chloride . . . interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest.").

[10] U.S. Nat'l Library of Med., *Nembutal Sodium* (Oak Pharm., Inc.), NDC Codes 76478-501-20, 76478-501-50, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5c380ab0-4386-48b6-80ab-ca594b23bc74.

tween one and two-and-a-half milligrams.[11] But corrections officials use doses ranging between 50 milligrams to 500 milligrams when using midazolam to carry out an execution.[12]

Corrections officials who use drugs at high doses that have not been subject to scientific study, and for purposes the manufacturer never intended, are left to stumble in the dark. If manufacturers only studied a drug's safety and efficacy at low dose, radically amplifying that dose could lead to adverse effects for individuals with certain medical conditions or to undesirable interactions with other drugs in the execution protocol.[13] Moreover, determining if the drug will have

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[11] U.S. Nat'l Library of Med., *Midazolam—Midazolam Hydrochloride Injection, Solution* (Fresenius Kabi USA, LLC), NDC Codes 63323-411-10, 63323-411-12, 63323-411-13, 63323-411-15, 63323-411-18, 63323-411-25, 63323-412-02, 63323-412-03, 63323-412-05, 63323-412-06, 63323-412-10, 63323-412-13, 63323-412-18, 63323-412-25, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a91ce254-14a3-4cbf-8ab8-5da252aa3fdc#d684b678-cbae-4e0d-a572-40b8fb2a50dd; *see also Arthur v. Dunn*, 137 S. Ct. 725, 728 (2017) (Sotomayor, J., dissenting) (describing expert testimony that "*clinical* doses of midazolam . . . typically range from 2 to 5 mg" as compared to "non-clinical, *lethal* doses" that are orders of magnitude higher).

[12] *See* Ariz. Dep't of Corrs., *Consulting Services for Assessment and Review of Execution Protocols* 40-43 (Dec. 15, 2014), https://corrections.az.gov/sites/default/files/documents/PDFs/arizona_final_report_12_15_14_w_cover.pdf; *Glossip*, 135 S. Ct. 2,734-35 (noting execution protocols requiring 100 and 500 milligrams of injectable midazolam).

[13] *See, e.g.*, Jahan Porhomayon et al., *The Impact of High Versus Low Sedation Dosing Strategy on Cognitive Dysfunction in Survivors of Intensive Care Units: A Systematic Review and Meta-Analysis*, 7 J. Cardiovas. Thorac. Res. 43, 47 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4492176/pdf/JCVTR-7-43.pdf (concluding that "higher sedation dosing

the desired effect at an unstudied dose may depend on guesswork and extrapolation. *See, e.g.*, *Glossip*, 135 S. Ct. at 2741 (discussing expert testimony acknowledging that "there is no scientific literature addressing the use of midazolam as a manner to administer lethal injections in humans"); *id.* at 2784 (Sotomayor, J., dissenting) (pointing to the lack of "scholarly research" to support the State's claims about the drug's effects at high doses).

Operating without the benefit of rigorous scientific research, states may be forced to proceed through trial and error. And the errors can be ghastly: uncertainty about a drug's efficacy and dosing appear to have contributed to "horrific execution[s]" in which a prisoner appears "to be in great pain" because the drug did not work to anesthetize the prisoner in the way corrections officials intended. *Arthur*, 137 S. Ct. at 727, 733 (Sotomayor, J., dissenting); *see also Glossip*, 135 S. Ct. at 2790 (Sotomayor, J., dissenting) (describing a botched execution in which the prisoner "awoke" after 100 mg of midazolam was administered and "began to writhe and speak" before he eventually died); Mark Berman, *The Prolonged Arizona Execution Used 15 Doses of Lethal Injection Drugs*, Wash. Post (Aug. 4, 2014) (describing an execution that lasted nearly two hours despite 15 injections of midazolam, which totaled 750 milligrams).

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strategy will impact cognitive function in critically ill patients both medically and psychologically").

B. Facilitating Death Through Lethal Injection Is Not A Medically Accepted Off-Label Use Of Prescription Medicines.

Of course, although FDA only approves a drug for particular uses, doctors may prescribe drugs "for both FDA-approved and -unapproved uses." *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012). Indeed, off-label drug use is an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). "FDA approved indications" are thus "not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient." *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989).

But the central premise of off-label drug use is that it is guided by the scientifically informed judgments of medical professionals making individualized assessments of "a patient's needs and individual characteristics."[14] Accordingly, off-label use will be in a patient's best interest only if it is backed by "credible, published scientific data supporting the use of the drug in that manner."[15] The off-label use of injectable drugs to carry out executions subverts that basic standard.

First, as noted, pp. 7-10, *supra*, there are no rigorous empirical studies of the effects of injectable drugs

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[14] Katrina Furey & Kirsten Wilkins, *Prescribing "Off-Label": What Should a Physician Disclose?*, 18(6) AMA J. Ethics 587, 590 (2016), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-05/ecas3-1606.pdf.

[15] *Id.*

when used at high dosages for the purpose of lethal injection. *E.g.*, *Glossip*, 135 S. Ct. at 2741. Nor could there be, given the grave ethical concerns with such testing. Instead, states are left to observe anecdotally the effects drugs have when used in executions, and to make ad hoc adjustments when a particular drug (or combination of drugs) does not perform as expected. *Id.* at 2746. Reliance on anecdote, without any effort to obtain statistical significance or control for a particular patient's medical history, is antithetical to scientifically accepted standards for prescribing medication.

Second, the choice of drugs and dosing levels are determined by pre-set execution protocols,[16] which leave very little room for consideration of how the "individual characteristics" of an inmate might impact a drug's effect.[17] Indeed, in many cases, there is no individualized medical judgment being exercised at all, because the medical community condemns participation in the execution process. *See* Part III, *infra*. As a result, lethal injection protocols are often administered by individuals who lack the qualifications necessary to make informed medical judgments and to adjust how drugs are administered to the conditions of a particular prisoner. The "use of non-FDA-approved drugs in executions" thus violates the enabling premise of off-label use—deference to the practice of medicine."[18] "Off-label use rests on the implicit assumption that medical

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[16] Ariz. Dep't of Corrs., *supra*, at 40-43.

[17] *See* Furey & Wilkins, *supra*, at 590.

[18] Rose C. Goldberg, *Safe and Effective for Human Executions? Glossip v. Gross and the Eighth Amendment Bar Against Off-Label Drug Lethal Injection*, 68 Stan. L. Rev. Online 1, 4 (2015).

judgment is sufficiently risk mitigating, but this protection is absent" in the lethal-injection context.[19]

This case illustrates the point. Petitioner suffers from a rare medical condition called cavernous hemangioma that causes inoperable blood-filled tumors to grow in his throat and around his face, head, and neck. Pet. App. 6a. His expert reports that, among other issues, Petitioner's tumors will likely cause him to lose the ability to manage his airway after the lethal drug dose begins to flow, and that, as a result, he will experience extreme pain associated with suffocation. *See* Pet. App. 115a-116a. Moreover, according to Petitioner, the anonymous State medical personnel who will assist in his execution will receive limited information about his medical history, leaving them with little ability to modify the State's protocol to address his condition—even assuming they have the expertise and experience to do so. *See* Petr.'s Br. 13. Petitioner is not alone in this regard; other prisoners have likewise identified "individual health attributes" that make the State administration of drugs for non-approved uses especially dangerous. *See, e.g., Arthur*, 137 S. Ct. at 728 (Sotomayor, J, dissenting) (discussing expert testimony that a prisoner's age and "cardiovascular issues" "create[d] a constitutionally unacceptable risk of pain" from the administration of midazolam).

All told, powerful injectable drugs such as sedatives and barbiturates are being used at untested levels for an untested purpose, often without adequate physician supervision. Under such circumstances, the off-label use of these prescription drugs is medically irresponsible. AAM and its members oppose it.

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[19] *Id.*

C. Diverting Drugs From Patient Treatment For Use In Executions Has Unintended Negative Consequences.

The practice of using powerful sedatives, barbiturates, and paralytics for unstudied purposes at unstudied dosing levels also creates market distortions that may negatively impact access to certain drugs. Corrections officials sometimes stockpile drugs in significant quantities—a practice that has real consequences for public health.[20] Drugs like vecuronium bromide and potassium chloride are considered "essential medicines" by the World Health Organization,[21] but they are in short supply.[22] Yet a 2017 study found that just four states had stockpiled enough of these drugs to treat 11,257 patients—if the drugs were used as intended for medical treatment rather than in executions.[23]

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[20] *See* Ed Pilkington, *States Are Stockpiling Lethal Injection Drugs That Could Be Used to Save Lives*, The Guardian (Apr. 20, 2017), https://www.theguardian.com/world/2017/apr/20/states-stockpiling-lethal-injection-drugs-arkansas-execution ("Arkansas has stockpiled sufficient supplies . . . to treat 1,800 patients in potentially life-saving operations. . . . Virginia[] has sufficient stocks of drugs used in its lethal injection protocol to treat almost 5,000 patients in critical operations.").

[21] World Health Org., 19th WHO Model List of Essential Medicines 37, 40 (Apr. 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf?ua=1.

[22] Pilkington, *supra*. In fact, more than half the drugs currently used in state execution protocols are experiencing shortages, as reported by FDA and the American Society of Health-System Pharmacists.

[23] *Id.*

Many drug manufacturers, including AAM's members, have worked to stop the diversion of their products away from legitimate medical uses by implementing supply-chain controls to prevent the sale of their medicines for use in capital punishment.[24] The implementation and enforcement of these controls furthers drug manufacturers' legitimate business interest in (a) ensuring that their products are used only for their intended therapeutic purposes, (b) avoiding the reputational cost of being associated with facilitating executions, including executions that go poorly, and (c) reducing the risk of shareholder disinvestment.

But despite efforts to prevent distribution of the drugs to correctional facilities, states have often found ways to secure those drugs for use in capital punishment—sometimes under questionable circumstances. *See* Richard A. Oppel Jr., *Nevada Execution Is Blocked After Drugmaker Sues*, N.Y. Times (July 11, 2018) (describing a temporary restraining order to block Nevada's use of midazolam in an execution based on the manufacturer's suit alleging that the drug was purchased by Nevada under false pretenses, and in violation of the company's distribution controls); Compl., *McKesson Medical-Surgical Inc. v. State of Arkansas et al.*, Circuit Court of Pulaski Cty., Arkansas Div. (Apr. 14, 2017) (alleging that the Arkansas Department of Corrections purchased vecuronium from McKesson, a leading pharmaceutical distributor, by concealing its intent to use the drug in executions, which violated the manufacturer's terms of sale). As a result, drugs may be used for purposes that AAM members did not intend. Moreover, drug manufacturers are limited in

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[24] *See* Erik Eckholm, *Pfizer Blocks the Use of Its Drugs in Executions*, N.Y. Times (May 13, 2016).

their ability to discover whether their distribution policies have been subverted, because several states have adopted secrecy laws that are designed to keep information related to executions confidential—including information about the source of medicines that are used in lethal injections.[25]

That outcome not only conflicts with the policies and values of AAM and its members—and risks significant damage to their reputations—but it also carries the prospect of legal liability. For example, one family of an executed inmate brought a product liability suit against a midazolam manufacturer and a pharmaceutical wholesaler because the manufacturer's product was used in an execution that allegedly caused severe pain and suffering. *See* First Am. Compl. ¶ 162, *McGuire v. Mohr*, No. 14-cv-93 (S.D. Ohio filed Dec. 5, 2014).[26] Continued misuse of drugs by corrections officials may invite future suits against legitimate drug companies, and could ultimately harm patients by contributing to drug shortages.

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[25] *See* The Legal Injection Information Center, *Respecting Corporate Contracts: State-by-State Risk Index* (July 2018), http://lethalinjectioninfo.org/wp-content/uploads/2018/06/State-by-State-Risk-Index.pdf.

[26] The plaintiffs in that case later dropped their suit when the state changed its execution protocol to use other drugs. *See* Jeremy Pelzer, *Dennis McGuire's Family Drops Lawsuit Challenging His Controversial Execution*, cleveland.com (Feb. 3, 2015, 12:59 PM), https://www.cleveland.com/open/index.ssf/2015/02/dennis_mcguires_family_drops_l.html

II. As Members Of The Medical Community, Pharmaceutical Manufacturers Believe That Their Products Should Be Used Only To Treat And Heal Patients.

AAM and its members are opposed to the use of their products for lethal injection because they intend for their products to treat and heal individuals, not to contribute to suffering or end lives. This reflects the basic Hippocratic principle that underlies medical treatment: "do no harm."

Organizations whose members are tasked with direct patient care have opposed lethal injections unequivocally. The American Medical Association, for example, has stated for decades that "as a member of a profession dedicated to preserving life when there is hope of doing so, a physician must not participate in a legally authorized execution."[27] The American Board of Anesthesiology also adheres to that view, and it has even taken the position that members who participate in executions by lethal injection should lose their certifications.[28] The American Nurses Association likewise opposes lethal injection on the ground that "[t]he ethi-

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[27] Am. Med. Ass'n, Code of Medical Ethics Opinion 9.7.3, https://www.ama-assn.org/delivering-care/capital-punishment.

[28] *See* Am. Bd. of Anesthesiology, Inc., Commentary: Anesthesiologists and Capital Punishment (May 2014), http://www.theaba.org/PDFs/BOI/CapitalPunishment Commentary; *see also* Br. of Amicus Curiae Am. Soc'y of Anesthesiologists as *Amicus Curiae* Supporting Neither Party at 2, *Baze v. Rees*, No. 07-5439 (U.S. filed Nov. 13, 2007) ("[T]he Society eschews physician participation in executions as unethical and contrary to the duty of physicians as healers[.]").

cal principle of nonmaleficence requires that nurses act in such a way as to prevent harm, not to inflict it."[29]

Other medical professionals strongly oppose lethal injection on similar grounds. The American Pharmacists Association "discourages pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care."[30] And the American Public Health Association, whose constituency carries out "the majority of executions in the United States," states that participation in lethal injection procedures "is a serious violation of ethical codes and should be grounds for active disciplinary proceedings."[31]

Like the medical professionals responsible for patient care, pharmaceutical companies believe that their products should be used only to heal, not to harm.

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[29] Am. Nurses Ass'n, *Position Statement: Capital Punishment and Nurses' Participation in Capital Punishment* 6 (2016), https://www.nursingworld.org/~4906a3/globalassets/docs/ana/practice/official-position-statements/capital-punishment-position-statement_2017.pdf.

[30] Am. Pharmacists Ass'n, *APhA House of Delegates Adopts Policy Discouraging Pharmacist Participation in Execution* (Mar. 30, 2015), https://www.pharmacist.com/press-release/apha-house-delegates-adopts-policy-discouraging-pharmacist-participation-execution.

[31] Am. Pub. Health Ass'n, *Participation of Health Professionals in Capital Punishment* (Jan. 1, 2001), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/13/02/participation-of-health-professionals-in-capital-punishment.

CONCLUSION

Although AAM takes no position on capital punishment *per se*, its members are strongly opposed to the use of FDA-approved medicines to carry out executions. AAM believes that, in ruling on Petitioner's Eighth Amendment claim, the Court should take into account the serious problems created when prescription drug products are used for purposes that have not been scientifically studied and are completely antithetical to what their manufacturers intended and to what FDA approved.

Respectfully submitted.

JEFFREY K. FRANCER
ASSOCIATION FOR
ACCESSIBLE MEDICINES
601 New Jersey Ave., NW
Washington, DC 20001

BRIAN T. BURGESS
Counsel of Record
JAIME A. SANTOS
ANDREW KIM
GOODWIN PROCTER LLP
901 New York Ave., NW
Washington, DC 20001
(202) 346-4000
bburgess@goodwinlaw.com

July 23, 2018